

REMARKS

Claims 1 through 5 and 12 through 25 were presented for examination in the present application. The instant amendment cancels claims 1 through 4, 12 through 14, and 25 without prejudice. Thus, claims 5 and 15 through 25 are presented for consideration upon entry of the instant amendment.

The Office Action asserts that the disclosure of the prior-filed application 2003901971 in Australia, fails to provide adequate support or enablement in accordance with 35 U.S.C. 112. Specifically, the Office Action states that "a screw thread being on the head of the shaft (see claims 1-5, 12-15, and 20-22) is not supported in the disclosure of the prior-filed application". Applicant notes that claims 1 through 4 and 12 through 14 have been cancelled thus rendering the objections to priority moot. In addition, claim 15 has been amended accordingly. As such, Applicant respectfully submits that the Office Action's objection based on priority has been addressed in full, and that the priority date for the present application is April 23, 2003.

The drawings were objected to under 37 CFR 1.83(a). As previously noted, claims 1 and 2 have been cancelled rendering the objections to the drawings moot. Reconsideration and withdrawal of the objections to the drawings are respectfully requested.

Claims 1 through 5 and 12 through 15 were rejected under 35 U.S.C. 112, second paragraph. Claims 1 through 4 and 12 through 14 have been cancelled thus rendering the rejections to these claims moot. Claim 5 has been amended to depend from independent claim 16 thereby nullifying the rejection to claim 5. Claim 15 has been amended accordingly. Reconsideration and withdrawal of the rejections to claims 1 through 5 and 12 through 15 are respectfully requested.

Claims 16 through 19, 23, and 24 were rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,827,285 ("Bramlet").

Without acquiescing to the Office Action's rejection, Applicant has amended claim 16 to incorporate the additional novel feature of "a retaining screw for engaging the first internal screw thread on the first screw portion and resting in abutment with the head, thereby substantially precluding rotation of the shaft relative to the first screw portion (emphasis added)".

Support for the retaining screw is found in the specification as originally filed on page 8 at lines 13-25. No new matter has been added.

There is no such retaining screw provided in any cited prior art document. As such, the cited prior art does not disclose or suggest the elements of independent claim 16. Claims 17 through 19, 23, and 24 depend from independent claim 16. As such, the cited art fails to disclose or suggest the elements of claims 17 through 19, 23, and 24 for at least the reasons set forth above with regard to claim 16.

Further, It is noted that the Office Action considers Bramlet to disclose the feature recited in claim 19, in which the "first screw portion is a collar screw with an opening along its length for receiving a length of said longitudinal shaft". However, Applicant does not find any discussion of this feature anywhere in Bramlet. Given the absence of such a disclosure, it is submitted that the feature claimed in claim 19 is novel, and not disclosed or suggested by Bramlet.

Applicant also notes that the Office Action considers Bramlet to disclose the feature recited in claim 23, in which "the longitudinal shaft is flexible". In support of the rejection, the Office Action merely states that "the shaft would be at least flexible to a small degree". Applicant, however, does not find support for this statement anywhere in the disclosure of Bramlet. There is no disclosure of the claimed feature of a flexible shaft being readily flexible, or functionally flexible as the ambit of claim 23. Since the Office Action has not shown the existence of the claimed feature in Bramlet, it is submitted that the Office Action has failed to demonstrate that the feature of claim 23 lacks novelty.

In view of the reasons set forth above, Applicant respectfully requests the reconsideration and withdrawal of the rejections to claims 16 through 19, 23, and 24.

Claims 1, 3 through 5, 12, 13, 15, 16, and 20 through 22 were rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. 2005/0143735 ("Kyle") in view of U.S. Patent No. 5,498,265 ("Asnis"). Claim 14 was rejected under 35 U.S.C. 103(a) as being unpatentable over Kyle in view of Asnis, and further in view of U.S. Patent No. 3,996,931 ("Challender"). Claim 25 was rejected under 35 U.S.C. 103(a) as being unpatentable over Bramlet, and further in view of Callender.

As noted previously, claims 1 through 4 and 6 through 14 have been cancelled. Claim 5 has been amended to depend from claim 16.

Claims 15 and 16 have been amended to recite the feature of a retaining screw (or a locking step involving use of said retaining screw) which is threadedly engaged with an internal thread on the first screw portion to rest in abutment with the shaft head, thereby substantially precluding rotation of the shaft relative to the first screw portion. This feature is illustrated in the embodiment of Figure 3 (reference numeral 14) of the instant application. This feature is not, however, disclosed or suggested in the prior art.

The Office Action rejects the retaining screw as recited in claim 25 under 35 USC §103 as being unpatentable over Bramlet as applied to claim 16 and further in view of Callender Jr (US 3,996,931). The Office concedes that Bramlet does not specifically teach a retaining screw in order to retain a second member in a first member. The Office Action asserts, however, that it would have been obvious to someone of ordinary skill in the art at the time of the invention to include a retaining screw in the invention of Bramlet, in view of Callender Jr in order to retain the second screw portion in the first screw portion.

Callender Jr discloses nailing apparatus for fastening fractured femoral bones.

The device has a fixed sleeve member 26 that is attached to the shaft of the femur 18. The shaft member 28 of the device with far screw portion 30 is inserted through sleeve member 26 and across the fracture holding the fracture in compression by means of an adjustable limit screw assembly 32 which draws the shaft member down against the sleeve member.

According to Callender and the teachings of US 3,374,786 referenced therein, the limit screw assembly includes an adjustable stop element having an externally threaded shank portion 42 and a head 44 which abuts the axial end portion 46 of the guide sleeve in order to limit *axial* displacement of the shaft member relative to the guide sleeve. The stop element is adjustable by means of an elongated screw member 48 provided with external threads directed oppositely to the external threads on the shank portion 42, and which is threadedly engageable with the rod member 36 of the shaft. Hence, screw assembly 32 provides *axial* control, limiting *translational movement* of the shaft member with respect to the sleeve member (via the limit screw assembly), but does not provide rotational control as is claimed in the instant application.

According to Callender, sleeve member 26 (identified by the Office as "first member") is in a fixed position on the bone (as dictated by fasteners 22 which are attached to the shaft of the femur) and does not undergo rotation. Shaft member 28 (identified by the Office as "second member") rotates within the sleeve member. Applicant notes that according to Callender, rotation of the femoral head section (in which the shaft member is anchored) against the sleeve member is controlled by use of keyway grooves 34 and 36 and key 50 carried by the sleeve member, and not by a retaining screw. These keyway grooves also limit excessive telescoping and protrusion of the shaft member laterally into the muscle. This mechanism is entirely distinct from the retaining screw recited in the instant application.

The teachings of Callender are in contrast with the instant invention, in which the first and second screw portions are both rotatable independently of one another while positioned in the bone. The ability to perform independent rotation of the first and

second screw portions in the instant invention facilitates engagement in the bone of the first (near) and second (far) screw threads independently so as to perform controlled and discretionary rotation of either screw portion separately or connectedly, in either direction. This permits relative movement of the near or far bone segment relative to the far or near screw portion, or complete translation of the device as a unitary assembly in or out of the bone. The flexibility and ability to control independently the near and far screw portions gives the surgeon the ability to perform optimal reduction and compression of the fracture, without either collar protruding beyond the confines of the bone in which the fixation device is deployed. Clearly this is not possible in Callender, since the sleeve member (i.e. the first portion as identified in the Office Action) is anchored in a fixed position on the femur.

Once the desired relationship is achieved between the first and second screw portions of the instant invention, their relative position is locked in place by application of the retaining screw. This provides the necessary resistance to inadvertent torque actions on the bone fragments which might otherwise cause rotation of one screw portion, relative to the other.

Given that the screw assembly 32 referenced by the Office in Callender is distinct from the retaining screw recited in the instant application, Applicant submits that Callender does not correct the deficiency of Bramlet.

Applicant notes that Bramlet discloses a retainer apparatus 50 having a body portion 54 with a cross sectional configuration that generally corresponds to the cross-sectional configuration of a counter bore in the second fastener to hold the connector against rotation. Importantly, the cross sectional configuration of the retainer apparatus is selected to perform frictional engagement in combination with the counterbore in the second fastener, thereby preventing rotation of the retainer apparatus itself, but not relative rotation of the fastener elements. Thus, in practice the retainer apparatus is inserted axially into bore 38 and is not threadedly engaged as is the case with the claimed retaining screw. An annular ring 58 having an outside diameter generally equal

to the inside diameter of the channel 48 of the connector 40 into which the retainer apparatus is inserted, is formed of a material that allows the ring to compress and subsequently snap into the channel 48 and combine with surface 49 of channel 48 to prevent inadvertent axial displacement (i.e. removal) of the element 52. Forcible retraction of the retainer apparatus is required to overcome the click-fit of the annular ring within the channel prior to removal of the surgical screw assembly from the bone for adjustment, or after the fracture has repaired. Clearly it is undesirable to require application of force to disconnect and retract the retainer apparatus from the screw, particularly adjustment of screw placement is required during initial fixation of a fracture or in the early stages of healing as this can seriously and adversely affect patient outcome.

In contrast, the retaining screw of the instant invention is threaded and is inserted by rotation of the retaining screw within the internally threaded region of the first screw portion, which has corresponding internal thread with which the retaining screw engages, to finally rest in abutment with the end surface of the shaft head thereby substantially precluding rotation of the head (and longitudinal shaft extending therefrom) with respect to the first screw portion. Advantageously, the retaining screw may rest entirely within the screw portion without protruding from the fixation device. Moreover, if necessary, the retaining screw can be removed without force, simply by using a tool (such as a screwdriver) to unscrew the retaining screw, retracting it from within the first screw portion. This permits adjustment of the screw portions, and removal of the entire screw e.g. after healing. This feature and its advantages is not found in the disclosure of Bramlet or of Callender when considered alone or in combination.

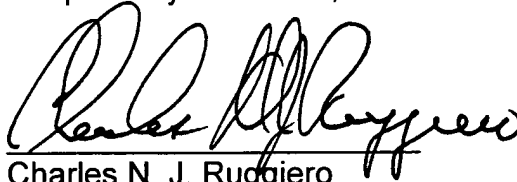
Applicant submits, therefore, that the cited art fails to disclose or suggest the elements of independent claims 15 and 16. Claims 15 and 16 are in condition for allowance. Claims 5, 20 through 22, and 25 depend from independent claim 16 and are in condition for allowance for at least the reasons set forth above with regard to claim 16. Reconsideration and withdrawal of the rejections to claims 5, 15, 16, 20 through 22, and 25 are respectfully requested.

In view of the above, it is respectfully submitted that the present application is in condition for allowance. Such action is solicited.

If for any reason the Examiner feels that consultation with Applicant's attorney would be helpful in the advancement of the prosecution, the Examiner is invited to call the telephone number below.

Respectfully submitted,

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A handwritten signature in black ink, appearing to read "Charles N. J. Ruggiero", written over a horizontal line.

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